K031776
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JUL 25 2003

510(k) Summary

Date Prepared: July 14, 2003

Submitter:

Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:

Ronald W. Bennett
Principal Regulatory Affairs Specialist

Phone: (763)-391-9086
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Device Name and Classification:

Trade Name: MC2X™ Multi-Stage Venous Cannula

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: Two Stage Venous Cannula
K915268

Extracorporeal Circuit with Bio-Active Surface
K891687

Device Description:
The MC2 family of cannula, including the new MC2X™ Multi-Stage Venous Cannula, are one piece, wire wound bodies with side ports in the distal tip, with ported atrial basket drainage and with an overall length of 15 ¼". Insertion depth marks aid in positioning the cannula. All are supplied sterile, are non-pyrogenic and are single use. The devices may include a Carmeda® coating.

Indication for Use
This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

Comparison to Predicate Device
The predicate devices are cannulae are Two Stage Venous Cannulae with the same general design characteristics. The predicate 510(k) devices currently marketed have the same indications for use. The predicate devices also provide drainage of the vena cava at the tip and provide atrial drainage. The currently marketed predicate devices include the same French size devices.

Summary of Performance Data
Collapse, flow, kink and tensile testing were conducted to ensure proper performance. In addition coverage, bio-activity, leaching and functional testing was performed on Carmeda® coated devices.

Conclusion
Medtronic Perfusion Systems has demonstrated that the modified MC2X Multi-Stage Venous Cannulae are substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Medtronic Perfusion Systems
c/o Mr. Ronald W. Bennett
Principal Regulatory Affairs Specialist
7611 Northland Boulevard
Brooklyn Park, MN 55428

Re: K031776
Trade Name: MC2X™ Multi-Stage Venous Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter cannula
Regulatory Class: Class II (two)
Product Code: DWF
Dated: July 14, 2003
Received: July 15, 2003

Dear Mr. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031776

510(k) Number (if known): K031776

Device Name:

MC2X™ Multi-Stage Venous Cannula

Indications for Use:

This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery up to six hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031776

(Optional Format 3-10-98)